DRAFT

To: Michelle Smith, M.D.

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From: FDDB

Date: December 22, 1999

Subject: Comments on Food and Drug Administration documents:

1) "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds""
2) "Guidance for Industry: Sampling and Microbial Testing of Sprout Irrigation Water During Sprout Production"

The above documents were emailed to Foodborne and Diarrheal Diseases Branch, CDC from CFSAN, FDA on October 22, 1999. The page numbers in the comments below refer to the versions of the above documents provided in that email.

"Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds

Overall CDC welcomes the strategy laid out by FDA in these documents to have sprouters test irrigation water during the sprouting process for evidence that growing sprouts are contaminated with Salmonellae or *Escherichia coli* O157. We believe this approach marks an important step forward in the efforts to improve the safety of raw sprouts, which have caused numerous outbreaks and hundreds of illnesses in the United States since 1995. Specific detailed comments are as follows:

Page	Comment
3	Paragraph 3. A more accessible reference for the last sentence on the amplification of pathogens during sprouting is: Jaquette CB, Beuchat LR, Mahon BE. Efficacy of chlorine and heat treatment in killing *Salmonella stanley* inoculated on to alfalfa seeds and growth and survival of the pathogen during sprouting and storage. Appl Environ

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Microbiol 1996;62:2212-2215.

4 Paragraph 1. A more accessible and up to date reference on recent outbreaks would be: Taormina PJ, Beuchat LR, **Slutsker L**. Infections associated with eating seed sprouts: an international concern. **Emerg Infect Dis** 1999;5:626-634.

5 Paragraph 2. We agree that microbial testing of spent irrigation water is an excellent strategy to improve sprout safety. Given the limitation of current approved decontamination methods however, perhaps this paragraph should conclude with a sentence also acknowledging the critical importance of continued research on alternative seed decontamination methods.

6 Paragraph 3. The sprout educational video is will be a useful source of information on safer production practices for sprout growers; we would note that CDC has also been a collaborator in the process of developing this video.

7 Paragraph 3. Would consider modifying the first sentence to "Failure of sprout growers to adopt effective preventive controls such as those outlined in this guideline document..."

"Guidance for Industry: Sampling and Microbial Testing of Sprout Irrigation Water During Sprout Production" (Appendix 1)"

10 Paragraph 2. It may be helpful to at least mention some of the important components of the Good Agricultural Practices similar to the approach taken in the next paragraph, where an example is given of important hazard control points during seed conditioning, storage, and transportation.

12 Paragraph 2. The approved treatments for seed decontamination should be listed here. As we understand it, there is currently only one; if this is the case it should be clearly stated as such. It may be useful to mention here the importance of sprouters keeping clear and accurate records documenting appropriate seed decontamination procedures.

16 Paragraph 1. Would consider modifying the introductory sentence to provide an end date for the number of sprout-associated outbreaks; e.g " Raw sprouts have been associated with at least eleven foodborne illness outbreaks from 1995 through 1999".

17 Paragraph 1. It would be useful to provide an approximate time frame for when investigators will be sent to sprouting facilities. .

18-19 Paragraphs on testing. It maybe useful to provide a reference or source sprout growers can contact to obtain information on how to locate a qualified laboratory to conduct microbial testing.

19 Paragraph 4. The information on the utility of spent irrigation water as an indicator of the

types of microorganisms found in sprouts is of interest and central to the testing strategy. Is there a reference that can be cited that provides data that spent irrigation water is a good indicator, and that documents the fall-off in recovery between sprouts themselves and the irrigation water?

20 Last paragraph. Are the pathogen levels during the sprouting process referred to here based on data derived from experiments using irrigation water, or from earlier experiments with the sprouts themselves (e.g. Jacquette et al, Appl Env Microbiol, 1996)

22-23 Paragraph on 'What to sample and how much to collect'. The issue of 'mixed sprout' product should be briefly addressed; i.e., if an alfalfa/radish/clover mixed product is positive on microbial testing, then the lots used form sprouting that 'batch' from all seed types should be considered potentially contaminated in the absence of further more specific information.

30 The incubation temperature is inconsistently used; it is given as 35 $\pm$ 1 ° C on this page and a range of 35 °-37 °C on pages 36 and 37.

31 Second paragraph. It may be easier to follow the guidance if the sentence: "*Instruction for sprouts are given in italics*" is moved up to appear earlier in the document, such as to page 27.

32 Paragraph entitled "IV. Testing". It may useful to modify the sentence "Enrichment broth containing sub-samples are allowed to incubate *for a period of time"* to "Enrichment broth containing sub-samples are allowed to incubate *as described below in Step 5*."

33 Section II, step # 9 and #11. These steps refer to the use of plates, needles, and loops, but the procedures describing the use of these materials are not contained in the document (unless their use is described in the "kit's instructions for raw foods" as mentioned on page 36, section 4b.

CROSS FILE SHEET

File Number: 99D 4488/C71

See File Number: 99D 4489/C72